Summary of Product Characteristics for Prio Retino+

1. Access to Prio Retino+ software:

The Prio Retino+ software requires no installation on a computer. Indeed, this software is an online application accessible via the button Access PRIO RETINO+, from the Prio Breast Cancer page of Gaiha website.

2. Input data to Prio Retino+ software:

The proper functioning of Prio Retino+ software requires a fundus image of good quality of different possible formats.

The good practices for using Prio Retino+ requires :

> 1) a fundus image which is not black, blurred or with bad pixel resolution. The resolution of the fundus should ideally be greater than 1 million pixels, although a lower resolution may be sufficient if the image is of good quality

> 2) a fundus in '.png' or '.jpeg' or '.jpg' format

Finally, as long as the above criteria are met, the fundus image can be generated from several types of retinographs.

3. Backup of Prio Retino+ software analysis results:

The analysis results of Prio Retino+ can be downloaded or printed via the button "Print Prio Retino+ results to PDF".

4. GDPR compliance and deletion of analyzed data:

The Prio Retino+ software does not use personal data as an anonymous patient ID is required for each analysis.

The correspondence between this identifier and the patient's personal data (i.e. surname, first name, email, etc.) is known only by the healthcare professional, and/or the healthcare centre, which takes responsibility for recording the personal data.

The data analyzed by Prio Retino+ is destroyed after each re-initialization of the software as recommended in the context of its use.

Prio Retino+ is therefore compliant with the GDPR in the context of its use and its recommendations.